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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/198,779	11/24/1998	STEFAN A. BLEDIG	16517.214	2937

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ARNOLD & PORTER LLP
ATTN: IP DOCKETING DEPT.
555 TWELFTH STREET, N.W.
WASHINGTON, DC 20004-1206

EXAMINER	
ZHOU, SHUBO	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8-A.

Office Action Summary	Application No.	Applicant(s)	
	09/198,779	BLEDIG ET AL.	
	Examiner	Art Unit	
	Shubo "Joe" Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2003 and 13 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 13-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 13-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Applicant's amendment and request for reconsideration, filed on 9/3/03 and 2/13/04, are acknowledged and the amendments entered.

Currently, claims 1, and 13-18 are pending and under consideration.

Specification

The objection to the specification due to containing embedded hyperlink and/or other form or browser-executable code is hereby withdrawn in view of applicants' amendment to the specification.

Claim Rejections-35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, and 13-18 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicant's arguments filed 9/3/03 have been fully considered but they are not persuasive. Applicants argue that the examiner has failed to provide evidence that SEQ ID NO:1 does not function in the manner described by the specification, and asserts that an examiner must accept a utility asserted by an applicant unless the Office has evidence or sound scientific

reasoning to rebut the assertion. This is not found persuasive because the Office, in the previous Office action, has set forth all the evidence of sequence analysis demonstrating that SEQ ID NO:1 is a hybrid sequence with unknown function. Specifically, SEQ ID NO:1 is comprises its nucleotides of 1-121 encoding a corn protein phosphatase 2A regulatory subunit A and a small portion of its nucleotides similar to maize methionine adenosyltransferase. Further, nucleotides 122-158 of SEQ ID NO:1 are a stretch of unidentified "Ns". Therefore, a prima facie case exists that SEQ ID NO:1 is neither the complete sequence of methionine adenosyltransferase nor a fragment thereof. Furthermore, applicants argue that the specification provides extensive evidence that SEQ ID NO:1 encodes a polypeptide that is 92% homologous to a known methionine adenosyltransferase, and that the polypeptide functions as a methionine adenosyltransferase. This is not deemed persuasive because there is no such extensive evidence found in the specification. Only Table A on page 226 contains a line that appears to show that SEQ ID NO:1 is 92% identical to NCBI g17262, and there is no sequence comparison to support such assertion. The sequence searching analysis performed by the Office does not identify NCBI g17262 having a 92% identity with SEQ ID NO:1. Applicants further argue that the examiner has not provided evidence why the asserted utility for SEQ ID NO:1 as a probe for other molecules and as molecular polymorphism marker is not a specific and substantial utility. This is not deemed persuasive because such utility is generic to any nucleic acid and further research has to be performed to find any particular polymorphism markers and to link them to any particular phenotypes.

Given above, it is the examiner's position that the Office has indeed provided sound scientific reasoning in the previous Office action through sequence analysis why a person of ordinary skill in the art would have reasonable doubt that SEQ ID NO:1 encodes a polypeptide functioning as methionine adenosyltransferase, and would perform further research to confirm so.

Newly added claims 14-18 are rejected for the same reasons as applied to claims 1 and 13 as set forth in the previous office action and above.

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, and 13-18 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1 and 13-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments filed 9/3/03 have been fully considered but they are not persuasive. Applicants' argument is essentially on the ground that the specification provides adequate guidelines and experimentation with SEQ ID NO:1 to use it as an methionine adenosyltransferase is not undue. This is not found persuasive because as to SEQ ID NO:1, the specification only disclose in Table A that it is 92% identical to NCBI g17262 having a 92% and does not provide further sequence analysis. The specification may generally discusses methionine adenosyltransferase, but does not provide adequate guidelines for using SEQ ID NO:1, which is a hybrid nucleic acid comprising fragments of two enzymes linked by a stretch of unknown nucleotides, as a methionine adenosyltransferase. Since the sequence of SEQ ID NO:1 is novel and the prior art does not provide such guidelines either, a skilled practitioner would have to turn to trial and error experimentation for using such a hybrid nucleic acids as methionine adenosyltransferase without guidance from the specification or the prior art. As such, the results of the trial and error would be unpredictable, and would be undue.

Newly added claims 14-18 are rejected for the same reasons as that applied to claims 1 and 13 in the previous office action and that set forth above.

Claims 1, and 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed 9/3/03 have been fully considered but they are not persuasive.

Applicants argue that since the specification discloses the sequence of SEQ ID NO:1, it thus establishes possession of the claimed invention by applicants. This is not found persuasive for the following reasons:

Claim 1 appears to be drawn to a genus of polynucleotide including any polynucleotides comprising the nucleotide sequence of SEQ ID NO:1 that encodes a maize methionine adenosyltransferase or fragment thereof. While SEQ ID NO:1 may encode a fragment of a maize methionine adenosyltransferase, it does not contain a complete open reading frame encoding the full length maize methionine adenosyltransferase. Further, there is substantial variability among the species encompassed by the scope of the claim because the genus encompasses a variety of species which are yet to be discovered, such as full-length cDNA encoding the full-length maize methionine adenosyltransferase.

A description of a genus may be achieved by means of a recitation of a representative number of species, falling within the scope of the genus, or by means of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In the instant case, since the specification discloses only a species: a fragment of methionine adenosyltransferase encoded by SEQ ID NO:1, and, as set forth above, SEQ ID NO:1 is a partial cDNA that does not include any open reading frame of which it would be a part, the disclosure of one species, i.e. SEQ ID NO:1, would not be a representative number of species of the claimed genus. Further, since the claimed genus

encompasses species yet to be discovered, e.g. full-length cDNA, the disclosed structural feature, i.e. SEQ ID NO:1, does not "constitute a substantial portion" of the claimed genus. Therefore, the disclosure of SEQ ID NO:1 does not provide an adequate description of the claimed genus.

All factors considered, 1) partial structure of the DNAs that comprise SEQ ID NO:1, 2) the breadth of the claim as reading on genes yet to be discovered, and 3) the lack of correlation between the structure and the function of the enzyme encoded by the claimed nucleic acids; in view of the level of knowledge and skill in the art, one skill artisan in the art would not recognize from the disclosure that the applicant was in possession of the genus of polynucleotides encompassed by the scope of the claim.

Applicant further argue that the "disclosure of an extensive number of nucleic acid sequence encoding the specified enzyme or fragments thereof, e.g., SEQ ID NOS: 1-429 and 1635-2479, in combination with other appropriate language in fact does provide sufficient written description for claims within the genus claims". This is not found persuasive because not all the sequences of SEQ ID NOS: 1-429 and 1635-2479 are species for the same genus. On the contrary, they are distinct inventions, i.e. nucleic acid encoding different proteins or polypeptides based Table A on page 226 of the specification.

Claims 14-18 are rejected for the same reasons as that applied to claim 1 in the previous office action and that set forth above.

It should be noted that in examining the newly added claims 14-18, the limitation of "complement" in the claims is interpreted as follows: A complement of a first nucleic acid is a nucleic acid whose sequence is 100% matching and base-paring with each and every

corresponding base pair of the first nucleic acid based on the base-pairing principles of Watson and Crick, and the complement is the same as the first nucleic acid in length.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst William Phillips whose telephone number is 571-272-0548, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shubo (Joe) Zhou, Ph.D.

Patent Examiner

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER